

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
ALEXANDRIA DIVISION**

Kathleen M. Harris,	*	
Plaintiff	*	
	*	
versus	*	COMPLAINT and
	*	DEMAND FOR
MERCK & CO, INC., SCHERING-	*	JURY TRIAL
PLOUGH CORPORATION, and	*	
MERCK/SCHERING-PLOUGH	*	
PHARMACEUTICALS, LUPIN	*	
PHARMACEUTICALS, INC., TEVA	*	
PHARMACEUTICALS, INC., DR.	*	
REDDY'S LABORATORIES, INC.,	*	
RANBAXY LABORATORIES, INC.	*	
Defendants	*	

PLAINTIFF'S ORIGINAL COMPLAINT

PARTIES

1. Plaintiff, Kathleen M. Harris (hereinafter "Plaintiff") is an individual and citizen and resident of Pineville, Rapides Parish, Louisiana.
2. At all times relevant herein, Defendant, Merck & Company, Inc (hereinafter "Merck" or "Defendant") is a corporation organized and existing under the laws of the State of New Jersey, and maintains a principal place of business in New Jersey. Merck maintains its headquarters at One Merck Drive, Whitehouse Station, NJ 08889.
3. Upon information and belief, at all times relevant herein, Defendant, Lupin

Pharmaceuticals, Inc. (hereinafter “Lupin”) is a corporation organized and existing under the laws of the State of Delaware, and maintains a principal place of business at Harborplace Tower, 111 S. Calvert Street, Baltimore, Maryland 21202.

4. Upon information and belief, at all times relevant herein, Defendant, Teva Pharmaceuticals, Inc. (hereinafter “Teva”) is a corporation organized and existing under the laws of the State of Delaware, and maintains a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.
5. Upon information and belief, at all times relevant herein, Defendant, Dr. Reddy’s Laboratories, Inc. (hereinafter “Reddy”) is a corporation organized and existing under the laws of the State of New Jersey, and maintains a principal place of business at 200 Somerset Corp. Blvd., Bridgewater, New Jersey 08807.
6. Upon information and belief, at all times relevant herein, Defendant, Ranbaxy Laboratories, Inc. (hereinafter “Ranbaxy”) is a corporation organized and existing under the laws of the State of Delaware, and maintains a principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.
7. At all material times herein, Defendants were, and are, in the business of profiting from the design, manufacture, marketing, distribution and/or sale of the brand-name prescription drug Zocor, or its generic version, simvastatin.
8. At times relevant and material hereto, Defendants have sold, distributed and marketed

either directly or indirectly through third-parties or related entities, the pharmaceutical drugs Zocor or simvastatin in the State of Louisiana.

JURISDICTIONAL STATEMENT

9. This Court has jurisdiction pursuant to 42 U.S.C. sec. 1332. Plaintiff hereby avers that the amount in controversy in the above captioned matter exceeds the jurisdictional limits and that said controversy arises between citizens of different states as is required by the aforementioned state in order to invoke the “Diversity of Citizenship” Jurisdiction of this Court.
10. Venue is proper as Plaintiff is a Louisiana resident, her claims and causes of action arose in this judicial district, and a substantial part of the events giving rise to the Plaintiff’s claims occurred in this judicial district.
11. At all times relevant and material hereto, Defendant has conducted continuous and substantial business in the State of Louisiana.
12. At all times relevant and material hereto, the Defendant acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.
13. As more particularly pleaded below, Plaintiff maintains that the pharmaceutical drug, Zocor, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings as to the dangers associated with its use.
14. At all relevant times, defendant Merck was in the business of developing, researching,

selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling and/or marketing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Zocor.

15. At all relevant times, Defendant Merck did in fact develop, research, sell, distribute, design, manufacture, test, evaluate, license, label, and/or market, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Zocor.
16. Merck obtained FDA approval on Zocor 80 mg in approximately 1998 and began its distribution and sale through the United States thereafter. Zocor is the brand name used by Merck to market and distribute simvastatin.
17. Defendant Merck concealed the serious risks associated with Zocor, Merck's highest selling drug, prior to losing the patent protection and therefore was viewed as critical for Merck's profitability. Safety concerns over Zocor developed such as myopathy, including a rare form called rhabdomyolysis, which dramatically impacted Merck's sales.
18. Merck knowingly chose to market this product, despite its knowledge at product launch and its post-marketing data thereafter that use of Zocor carries significant risk factors. These adverse effects were revealed in a press release from the Food and Drug Administration (hereinafter "FDA") on March 19, 2010. The FDA press release was based upon information derived from clinical trials, observational studies, adverse event reports, and prescription use data. The FDA also used data from the SEARCH (Study of

the Effectiveness of Additional Reductions in Cholesterol and Homocysteine).

19. Plaintiff was prescribed, and took as directed, Defendants' drug Zocor or simvastatin for cholesterol from approximately August 2001 until January 2012.
20. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of their product Zocor or simvastatin, the Plaintiff suffered physical injury and damage, including but not limited to muscle and kidney problems.
21. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of their products Zocor or simvastatin, Plaintiff has in the past and will in the future experience physical injuries, pain and suffering, loss of enjoyment of life, lost wages, lost earning capacity, medical expenses, medical monitoring expenses, embarrassment and humiliation, fright and apprehension, emotional distress and other damages all of which are believed to be permanent.
22. Zocor is the brand name of simvastatin, a cholesterol lowering medication.
23. On March 19, 2010 the FDA issued a press release warning patients and healthcare providers of a greater risk of developing muscle injury, including rhabdomyolysis, for patients as they are prescribed higher doses (specifically 80 mg).
24. The SEARCH trial results revealed that more patients in the simvastatin 80 mg group developed myopathy compared to patients in the simvastatin 20 mg group. The

preliminary data showed that 11% of patients taking 80 mg developed rhabdomyolysis as compared to no patients in the 20 mg group.

25. In June 2011, the FDA approved a label change for simvastatin based upon the aforementioned results.
26. As previously noted, Merck had a significant market share based upon claims of Zocor's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of numerous sales representatives and massive direct-to-consumer advertising and physician sampling program.
27. As a result of such marketing, Zocor gained a significant market share in competition with other cholesterol lowering medications, that Merck would not have gained if Merck had not suppressed information about Zocor and/or made false representations of Zocor's superiority and efficacy.
28. If Merck had not engaged in this conduct, prescribers such as Plaintiff's prescriber would not have prescribed Zocor in patients, such as the Plaintiff, and would have switched from Zocor to safer products, or would have refrained wholly from any use of Zocor.
29. From approximately 1998 through the present, Merck continued to engage in a common scheme in marketing, distributing and/or selling Zocor under the guise that it was safe and efficacious for persons such as Plaintiff before, during and after Plaintiff developed kidney problems.

30. Plaintiff alleges that the suppression of this information constituted a common scheme by Merck to conceal material information from Plaintiff.
31. The actions of Defendants in failing to warn of the clear and present danger posed to others by the use of their drugs Zocor or simvastatin in suppressing evidence relating to this danger, and in making deliberate and misleading misrepresentations of fact to minimize the danger or to mislead prescribers and patients as to the true risk, constitutes such clear, blatant and outrageous conduct as to warrant the imposition of exemplary damages against Defendants.

FIRST CAUSE OF ACTION

32. Defendants are liable unto Plaintiff under the Louisiana Products Liability Act, R.S. 9:2800.51, *et seq.*, as Plaintiff's damages were proximately caused by the acts and/or omissions of defendants in the following particulars:
 1. Providing a product that was unreasonably dangerous in construction or composition;
 2. Providing a product that was unreasonably dangerous in design;
 3. Providing a product that was unreasonably dangerous because of inadequate warning about the product;
 4. Providing a product that was unreasonably dangerous because of nonconformity to express warranties.
29. Defendants knew, or should have known, that at the time their products left their control,

the design, nature and danger of the products' characteristics could cause Plaintiff's damage. Furthermore, defendants knew or should have known of the design, nature, and danger of the products' characteristics, but failed to inform the public and foreseeable users.

SECOND CAUSE OF ACTION

30. Defendants are by operation of law presumed to know that their products contained redhibitory defects which they failed to declare, so that defendants are further liable unto Plaintiffs under Articles 2520 *et seq.* of the Louisiana Civil Code. Such liability includes return of the purchase price, damages, including, but not limited to, mental anguish, and attorney's fees pursuant to Article 2545 of the Louisiana Civil Code and the presumption contained therein.
31. Separate and apart from, and in the alternative to, their status as manufacturers of their products, defendants entered into a contract of sales with Plaintiff as a result of Plaintiff's purchase of their products.

THIRD CAUSE OF ACTION

32. As a result of their breach of conventional obligations, defendants are obligors in bad faith per Articles 1994 and 1997 of the Louisiana Civil Code and liable unto Plaintiffs for all damages, foreseeable or not, that are a direct consequence of defendants' failure to perform, including, but not limited to, damages for pecuniary and non-pecuniary loss.

FOURTH CAUSE OF ACTION

33. Defendants, in the alternative, are liable unto Plaintiff under Article 2298 of the Louisiana Civil Code in that defendants were unjustly enriched without cause at the expense of the Plaintiff.

FIFTH CAUSE OF ACTION

34. Defendants have engaged in unfair or deceptive acts in violation of the Louisiana Unfair Trade Practices Act, LSA-R.S. 51:1401 *et seq.*, warranting the imposition of damages and attorneys' fees.

SIXTH CAUSE OF ACTION

35. To the extent that the evidence establishes that defendants have engaged in intentional misrepresentations, delictual fraud or have violated Art. 1953 of the Louisiana Civil Code, Defendants are liable unto Plaintiff for the imposition of damages and attorneys' fees.

SEVENTH CAUSE OF ACTION

36. Alternatively, defendants are liable unto Plaintiff under a theory of negligent misrepresentation. Specifically, defendants, because of their research and testing, assumed a duty to insure that the information they provided to physicians and hospitals about their products was accurate, correct and complete. However, because of lack of reasonable care or lack of skill or competence, defendants misrepresented that information causing physical injury and economic loss to Plaintiffs, who were intended

users of the products who relied upon the representations, to their detriment. Defendants owed a duty to Plaintiff because of defendants' knowledge that the ultimate purpose of their misrepresentations was to facilitate the sale of their products to users like Plaintiffs. Defendants knew that Plaintiff would receive those misrepresentations through physicians and hospitals who would channel defendants' products to users like Plaintiff.

EIGHT CAUSE OF ACTION

37. Defendants are liable unto Plaintiff for negligent infliction of emotional distress.
38. As the proximate result of the aforementioned acts and/or omissions of defendants, Plaintiff has sustained, or are certain to sustain, the following damages:
 1. Past and future loss of earnings;
 2. Past and future medical expenses;
 3. Nursing and rehabilitative care expenses;
 4. Loss of earning capacity;
 5. Past and future pain and suffering;
 6. Past and future mental anguish;
 7. Fear of future injury;
 8. Permanent disability;
 9. Loss of enjoyment of life.
39. Plaintiff pleads the doctrine of *res ipsa loquitur*.

40. Defendants acted together in concert in their actions, such that each is jointly liable for the acts of the other. Defendants shared many of the same officers and directors and made decisions in a uniform voice. Defendants and their subsidiaries had a complete unity of interest and control. Their objectives were common, not disparate, and their general corporate actions were guided or determined not by separate corporate consciousness, but by one.
41. Defendants are liable as solidary obligors under Article 1800 and 2324(A) of the Louisiana Civil Code.
42. The Complaint is filed within one (1) year of when Plaintiff first learned of a defect in defendants' products and the causal link between her injury and a defect in defendants' products. Plaintiff asserts the doctrine of *contra non valentem*.
43. Plaintiff requests and is entitled to trial by jury on all issues against all defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgement against Defendants, as follows:

- a. Awarding actual damages to the Plaintiff incidental to his purchase and use of Zocor or simvastatin in an amount to be determined at trial as well as medical monitoring;
- b. Awarding pre-judgement and post-judgement interest to the Plaintiff;
- c. Awarding the costs and the expenses of this litigation to the Plaintiff;

- d. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law;
and
- e. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

The plaintiff hereby demands a trial by jury on all counts and as to all issues.

Respectfully submitted:

Michael Hingle & Associates, LLC

Date: June 1, 2012

/s/ Michael Hingle
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